

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 24.01.2013

Version number 4

Revision: 24.01.2013

### 1 Identification of the substance/mixture and of the company/undertaking

- **Product identifier**
- **Trade name:** **IPS e.max Ceram: Dentin, Deep Dentin, Incisal, Transpa Incisal, Transpa, Essence, Gingiva, Margin, Intensive Margin**
- **CAS Number:**  
66402-68-4
- **EC number:**  
266-340-9
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the preparation**  
Manufacture of dental prothesis  
Fluorapatite glass-ceramic
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Ivoclar Vivadent AG  
Bendererstrasse 2  
FL-9494 Schaan  
FÜRSTENTUM LIECHTENSTEIN  
  
Tel: +423 235 35 35  
Fax: +423 235 33 60
- **Further information obtainable from:**  
Regulatory Affairs  
msds@ivoclarvivadent.com
- **Emergency telephone number:** +423 / 235 33 13

### 2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
The substance is not classified according to the CLP regulation.
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC** Not applicable.
- **Information concerning particular hazards for human and environment:** Not applicable.
- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Additional information:** Void
- **Other hazards**  
Dust generation  
Particular danger of slipping on leaked/spilled product.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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**Trade name: IPS e.max Ceram: Dentin, Deep Dentin, Incisal, Transpa Incisal, Transpa, Essence, Gingiva, Margin, Intensive Margin**

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### 3 Composition/information on ingredients

- **Chemical characterization: Substances**
- **CAS No. Description**  
66402-68-4 ceramic materials
- **Identification number(s)**
- **EC number: 266-340-9**

### 4 First aid measures

- **Description of first aid measures**
- **General information: No special measures required.**
- **After inhalation:**  
Supply fresh air; consult doctor in case of complaints.  
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:**  
Rinse with water.  
Generally the product does not irritate the skin.
- **After eye contact:**  
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.  
Mechanical effects only.
- **After swallowing:**  
Rinse out mouth and then drink plenty of water.  
If symptoms persist consult doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### 5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** The product is not flammable.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**  
Particular danger of slipping on leaked/spilled product.
- **Environmental precautions:** No special measures required.
- **Methods and material for containment and cleaning up:**  
Pick up mechanically.  
Ensure adequate ventilation.
- **Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.

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See Section 13 for disposal information.

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## 7 Handling and storage

- **Handling:**
- **Precautions for safe handling**  
Only adequately trained personnel should handle this product.  
Prevent formation of dust.  
Ensure good ventilation/exhaustion at the workplace.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**  
Keep container tightly sealed.  
Store in dry conditions.
- **Specific end use(s)** No further relevant information available.

## 8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Usual hygienic measures for dental practice.  
Wash hands before breaks and at the end of work.  
Keep away from foodstuffs, beverages and feed.  
Vacuum clean contaminated clothing. Do not blow or brush off contamination.  
Do not inhale dust / smoke / mist.
- **Respiratory protection:**  
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- **Recommended filter device for short term use:** Filter P2
- **Protection of hands:** Not required.
- **Material of gloves**  
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
- **Penetration time of glove material**  
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Safety glasses

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**Trade name: IPS e.max Ceram: Dentin, Deep Dentin, Incisal, Transpa Incisal,  
Transpa, Essence, Gingiva, Margin,  
Intensive Margin**

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### 9 Physical and chemical properties

· <b>Information on basic physical and chemical properties</b>	
· <b>General Information</b>	
· <b>Appearance:</b>	
<b>Form:</b>	Powder
<b>Colour:</b>	According to product specification
· <b>Odour:</b>	Odourless
· <b>Odour threshold:</b>	Not determined.
· <b>pH-value:</b>	Not applicable.
· <b>Change in condition</b>	
<b>Melting point/Melting range:</b>	Undetermined.
<b>Boiling point/Boiling range:</b>	Undetermined.
· <b>Flash point:</b>	Not applicable.
· <b>Flammability (solid, gaseous):</b>	Product is not flammable.
· <b>Self-igniting:</b>	Not determined.
· <b>Danger of explosion:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.
· <b>Vapour pressure:</b>	Not applicable.
· <b>Density:</b>	Not determined.
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not applicable.
· <b>Evaporation rate</b>	Not applicable.
· <b>Solubility in / Miscibility with water:</b>	Insoluble.
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not applicable.
<b>Kinematic:</b>	Not applicable.
· <b>Other information</b>	No further relevant information available.

### 10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability** Stable under normal handling and storage conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** None under normal conditions of storage and use.

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### 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** Mechanical effects only.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**  
The substance is not subject to classification according to the latest version of the EU lists.

### 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Generally not hazardous for water
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

### 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**  
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

· <b>European waste catalogue</b>	
08 02 99	wastes not otherwise specified

- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

- |                                  |      |
|----------------------------------|------|
| · <b>UN-Number</b>               |      |
| · <b>ADR, ADN, IMDG, IATA</b>    | Void |
| · <b>UN proper shipping name</b> |      |
| · <b>ADR, ADN, IMDG, IATA</b>    | Void |

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· <b>Transport hazard class(es)</b> · <b>ADR, ADN, IMDG, IATA</b> · <b>Class</b>	Void
· <b>Packing group</b> · <b>ADR, IMDG, IATA</b>	Void
· <b>Environmental hazards:</b> · <b>Marine pollutant:</b>	No
· <b>Special precautions for user</b>	Not applicable.
· <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.
· <b>UN "Model Regulation":</b>	-

### 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**  
The product is a medical device according to the EC-directive 93/42/EEC.
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### 16 Other information

*This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.*

· **Abbreviations and acronyms:**

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organization

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

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### 1 Identification of the substance/mixture and of the company/undertaking

- **Product identifier**
- **Trade name:** IPS e.max Ceram ZirLiner: Intensiv, Gingiva
- **CAS Number:**  
66402-68-4
- **EC number:**  
266-340-9
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the preparation**  
Manufacture of dental prosthesis  
Fluorapatite glass-ceramic
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Ivoclar Vivadent AG  
Bendererstrasse 2  
FL-9494 Schaan  
FÜRSTENTUM LIECHTENSTEIN
  
- **Tel:** +423 235 35 35  
**Fax:** +423 235 33 60
  
- **Further information obtainable from:**  
Regulatory Affairs  
msds@ivoclarvivadent.com
- **Emergency telephone number:** +423 / 235 33 13

### 2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
The substance is not classified according to the CLP regulation.

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- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC** Not applicable.
- **Information concerning particular hazards for human and environment:** Not applicable.

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- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Additional information:** Void
- **Other hazards**  
Dust generation  
Particular danger of slipping on leaked/spilled product.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### 3 Composition/information on ingredients

- **Chemical characterization:** Substances
- **CAS No. Description**  
66402-68-4 ceramic materials

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- **Identification number(s)**
- **EC number:** 266-340-9

#### 4 First aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:**  
Supply fresh air; consult doctor in case of complaints.  
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:**  
Rinse with water.  
Generally the product does not irritate the skin.
- **After eye contact:**  
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.  
Mechanical effects only.
- **After swallowing:**  
Rinse out mouth and then drink plenty of water.  
If symptoms persist consult doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

#### 5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** The product is not flammable.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

#### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**  
Particular danger of slipping on leaked/spilled product.
- **Environmental precautions:** No special measures required.
- **Methods and material for containment and cleaning up:**  
Pick up mechanically.  
Ensure adequate ventilation.
- **Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

#### 7 Handling and storage

- **Handling:**
- **Precautions for safe handling**  
Only adequately trained personnel should handle this product.  
Prevent formation of dust.

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- Ensure good ventilation/exhaustion at the workplace.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
  - Keep container tightly sealed.
  - Store in dry conditions.
- **Specific end use(s)** No further relevant information available.

### 8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
  - Usual hygienic measures for dental practice.
  - Wash hands before breaks and at the end of work.
  - Keep away from foodstuffs, beverages and feed.
  - Vacuum clean contaminated clothing. Do not blow or brush off contamination.
  - Do not inhale dust / smoke / mist.
- **Respiratory protection:**
  - In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- **Recommended filter device for short term use:** Filter P2
- **Protection of hands:** Not required.
- **Material of gloves**
  - The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
- **Penetration time of glove material**
  - The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Safety glasses

### 9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

<b>Form:</b>	Powder
<b>Colour:</b>	According to product specification
- **Odour:** Odourless
- **Odour threshold:** Not determined.
- **pH-value:** Not applicable.
- **Change in condition**

<b>Melting point/Melting range:</b>	Undetermined.
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**Trade name: IPS e.max Ceram ZirLiner: Intensiv, Gingiva**

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<b>Boiling point/Boiling range:</b>	Undetermined.
· <b>Flash point:</b>	Not applicable.
· <b>Flammability (solid, gaseous):</b>	Product is not flammable.
· <b>Self-igniting:</b>	Not determined.
· <b>Danger of explosion:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.
· <b>Vapour pressure:</b>	Not applicable.
· <b>Density:</b>	Not determined.
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not applicable.
· <b>Evaporation rate</b>	Not applicable.
· <b>Solubility in / Miscibility with water:</b>	Insoluble.
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not applicable.
<b>Kinematic:</b>	Not applicable.
· <b>Other information</b>	No further relevant information available.

### 10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability** Stable under normal handling and storage conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** None under normal conditions of storage and use.

### 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** Mechanical effects only.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**  
The substance is not subject to classification according to the latest version of the EU lists.

### 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.

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**Trade name: IPS e.max Ceram ZirLiner: Intensiv, Gingiva**

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- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Generally not hazardous for water
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

### 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**  
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

- **European waste catalogue**

08 02 99	wastes not otherwise specified
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- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

- |                                                                                  |                 |
|----------------------------------------------------------------------------------|-----------------|
| · <b>UN-Number</b>                                                               |                 |
| · <b>ADR, ADN, IMDG, IATA</b>                                                    | Void            |
| · <b>UN proper shipping name</b>                                                 |                 |
| · <b>ADR, ADN, IMDG, IATA</b>                                                    | Void            |
| · <b>Transport hazard class(es)</b>                                              |                 |
| · <b>ADR, ADN, IMDG, IATA</b>                                                    |                 |
| · <b>Class</b>                                                                   | Void            |
| · <b>Packing group</b>                                                           |                 |
| · <b>ADR, IMDG, IATA</b>                                                         | Void            |
| · <b>Environmental hazards:</b>                                                  |                 |
| · <b>Marine pollutant:</b>                                                       | No              |
| · <b>Special precautions for user</b>                                            | Not applicable. |
| · <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b> | Not applicable. |
| · <b>UN "Model Regulation":</b>                                                  | -               |

### 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**  
The product is a medical device according to the EC-directive 93/42/EEC.

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**Trade name: IPS e.max Ceram ZirLiner: Intensiv, Gingiva**

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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### 16 Other information

*This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.*

· **Abbreviations and acronyms:**

*RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)*

*ICAO: International Civil Aviation Organization*

*ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)*

*IMDG: International Maritime Code for Dangerous Goods*

*IATA: International Air Transport Association*

*GHS: Globally Harmonized System of Classification and Labelling of Chemicals*

*EINECS: European Inventory of Existing Commercial Chemical Substances*

*CAS: Chemical Abstracts Service (division of the American Chemical Society)*

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